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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,423	03/23/2001	Henrik Christian Hansen	P66431US0	7477

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EXAMINER
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KIDWELL, MICHELE M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 01/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/787,423

Applicant(s)

HANSEN ET AL.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments with respect to claims 1 – 9 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Walz, Jr. et al. (US 4,230,115).

With respect to claim 1, Walz, Jr. et al. (hereinafter "Walz") discloses a catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine, said package including an elongated, narrow part forming a tube for accommodation of a proximal part of the catheter (112), and a broader container part (area under 112), the proximal part of the catheter having an inner diameter and being adapted to be inserted into the urethra, said catheter including a sealing part for providing a seal between the catheter and the elongated part of the package during use (110), and further including a distal part formed as a tubular section having an inner diameter at least as large as the inner diameter of the proximal part of

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the catheter (portion encompassing and under reference numeral 110 in figure 18), said sealing part separating the proximal part of the catheter and the tubular distal part (figure 18), and a length of the tubular distal part being at least as long as a length of the elongated, narrow part of the package such that, in use, the tubular distal part is present within and extends through the length of the elongated, narrow part.

Regarding claims 11 and 14, see the rejection of claim 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 – 10, 12 – 13 and 15 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walz, Jr. et al. (US 4,230,115) in view of Israelsson (WO 97/26937).

The difference between Walz and claim 2 is the provision that the proximal part of the catheter has a hydrophilic coating.

Israelsson et al. (hereinafter "Israelsson") teaches a catheter wherein the proximal part has a hydrophilic coating as set forth on page 11, lines 3 – 6.

It would have been obvious to one of ordinary skill in the art to modify the proximal part of the catheter of Walz to provide a hydrophilic coating because the hydrophilic coating facilitates insertion of the catheter into the urethra as taught by Israelsson on page 1 in lines 11 – 19.

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With respect to claims 3 and 13, Israelsson teaches a catheter set characterized in that the set comprises a wetting fluid integrated into the package as set forth on page 18, lines 12 – 13.

With reference to claims 4, 7 and 15, the examiner contends that the claimed limitation is an obvious matter of design choice that does not patentably distinguish the claimed invention from the prior art. Walz discloses the tubular distal part of the catheter having at least the same inner diameter as the proximal part of the catheter. It would have been obvious to one of ordinary skill in the art to modify the diameter of any portion of the catheter since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

With reference to claims 5, 10 and 16, it would have been obvious to one of ordinary skill in the art to construct the tubular distal part of Walz from an extrudable, mouldable materials including those listed because it is well known in the art to construct disposable catheters from the claimed materials due to flexibility and cost effectiveness of the material.

Regarding claims 6 and 17, Walz discloses a catheter characterized in that the tubular part is transversely corrugated as set forth in figure 18. The examiner contends that the indenture at the end of the catheter may be considered as the transversely corrugated portion of the tubular part.

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With respect to claims 8 and 19, Israelsson teaches a catheter wherein the package is provided with at least one sealing device on an exterior side of the package as set forth on page 12, lines 12 – 15.

As to claims 9 and 20, the examiner contends that the claimed limitation is an obvious matter of design choice that does not patentably distinguish the claimed invention from the prior art. Israelsson teaches a catheter set with a sealing device as set forth in the rejection of claim 8. The substitution of one sealing device for another requires only a level of ordinary skill in the art.

Regarding claim 12, see the rejection of claim 2.

With reference to claim 16, see the rejection of claim 5.

With respect to claim 18, the examiner establishes the use of an extrudable, mouldable material with respect to the tubular distal part as set forth in the rejection of claims 5, 10 and 16. From this, it can be reasonably assumed that the catheter would be fully capable of performing the recited function because the extrudable, mouldable materials that disposable catheters are commonly formed from including polyethylene, polypropylene, natural rubber, synthetic rubber, etc. are all flexible to allow manipulation of the catheter prior to insertion and would all have sufficient stiffness to prevent kinking of the flexible container disclosed by Walz.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sheridan (US 3,853,130) is cited to show the knowledge in the art of formulating catheters from extrudable, mouldable materials (col. 7, lines 1 – 7).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

*Michele Kidwell*

Michele Kidwell  
January 22, 2004

*Glenn K. De*

GLENN K. DE  
PRIMARY EXAMINER